K011048

NOV 1 3 2001

SUMMARY OF SAFETY AND EFFECTIVENESS

DePuy
a Johnson & Johnson company

DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988
USA
Tel: +1 (219) 267 8143
Fax: +1 (219) 267 7196

NAME OF FIRM: DePuy, Inc.
700 Orthopaedic Drive
Warsaw, Indiana 46581-0988

510(k) CONTACT: Lynnette Whitaker
Manager, Regulatory Affairs

TRADE NAME: α-BSM® Bone Substitute Material

COMMON NAME: Bone Substitute Material, Bone Void Filler, Bone Graft Material

CLASSIFICATION: Not classified

DEVICE PRODUCT CODE: MQV

SUBSTANTIALLY EQUIVALENT DEVICES:

- α-BSM – Bone Substitute Material (K983009)
- Pro Osteon Implant 500R Resorbable Bone Graft Substitute (K990131)
- Osteoplast, Model POP200 (K991854)

DEVICE DESCRIPTION :

α-BSM, Bone Substitute Material is a synthetic, biocompatible, calcium phosphate implantable paste that hardens endothermically at body temperature and converts to an apatitic calcium phosphate. It is provided in single use packages containing either 1.0, 2.5, 5.0, or 10 grams of α-BSM powder in a mixing bulb, sterile mixing solution, an appropriately sized syringe, and a 16 gauge needle.

INTENDED USE:

α-BSM Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM is a bone graft substitute that resorbs and is replaced with bone during the healing process.

BASIS OF SUBSTANTIAL EQUIVALENCE:

The subject α-BSM Bone Substitute Material is identical in material, design, and method of use to the currently cleared and marketed α-BSM Bone Substitute Material for cranioplasty indications, and is identical in indications to the cleared ProOsteon 500R and Osteoplast devices. The safe and effective use of the device has been demonstrated through extensive testing, including a representative animal model. These facts provide all necessary information for a finding of substantial equivalency of the subject α-BSM Bone Substitute Material to the currently marketed predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 3 2001

Mr. Max Sherman
Vice President
Regulatory Affair, Clinical and Biostatistics
DePuy Orthopaedics, Inc.
700 Orthopaedic Drive
PO Box 988
Warsaw, Indiana 46581-0988

Re: K011048
α-BSM® Bone Substitute Material
Regulatory Class: unclassified
Product Code: MQV
Dated: October 11, 2001
Received: October 15, 2001

Dear Mr. Sherman:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if

applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative and
Neurological Devices
Office of Devices Evaluation
Center for Devices and
Radiological Devices

Enclosure

510(k) Number (if known) K011048

Device Name: α-BSM® Bone Substitute Material

NOV 1 3 2001

Indications for Use:

α-BSM® Bone Substitute Material is indicated for filling bone voids or defects of the skeletal system (such as the extremities, spine, and the pelvis) that are not intrinsic to the stability of the bony structure. These defects may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. α-BSM is a bone graft substitute that resorbs and is replaced with bone during the healing process.

Concurrence of CDRH, Office of Device Evaluation

Prescription Use _____ OR (Per 21 CFR 801.109) Over-The Counter Use

for Mark N. Melkerson

(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K011048